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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Stewart Cole

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EXAMINER

BABIC, CHRISTOPHER M

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/505,405	Applicant(s) COLE ET AL.	
	Examiner CHRISTOPHER M. BABIC	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7-14,19-22,60 and 61 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 and 23-59 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 61 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 7-9, and 11-14 is/are rejected.
- 7) ☒ Claim(s) 10,19-22 and 60 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claim(s) 1, 2, 5, 7-14, 19-22, 60, and 61 are pending. The following Office Action is in response to Applicant's communication dated December 23, 2008.

Election/Restrictions

Applicant's arguments are noted. The restriction requirement was made FINAL for the reasons set forth in the NON-FINAL Office Action dated August 18, 2008.

Sequence Rules Compliance

In view of Applicant's amendment to the specification, the instant application now complies with the Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures set forth in 37 C.F.R. §§ 1.821-1.825.

Specification

The objection to the specification has been withdrawn in view of Applicant's amendments.

Claim Objections - Withdrawn

Claim 6 has been cancelled. Applicant's claim amendments are sufficient to overcome the objection of claim(s) 9 and 14.

Claim Objections - Maintained

Claims 19-22 and 60 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). The claims recite dependency to claim 14, which is multiply dependent. Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112 - Indefiniteness - Withdrawn

Claim 3 has been cancelled. Applicant's claim amendments are sufficient to overcome the rejection of claim(s) 5 presented in the Office Action dated August 18, 2008.

Claim Rejections - 35 USC § 102 - Maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 5, 7-9, and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (U.S. 5,474,796).

With regard to claims 1, 2, and 7-9, Brennan teaches the production of a solid support comprising immobilized extendable oligonucleotides that represent every possible permutation of the 10-mer oligonucleotide (col. 9, example 4, for example). Thus, the product of Brennan inherently contains oligonucleotides that possess 100% identity or homology to 10-mer segments of SEQ ID NO: 1 and 4 as well as oligonucleotides that are perfectly complementary to 10-mer segments of SEQ ID NO: 1 and 4, i.e. options C and D of the claimed invention. Thus, Brennan anticipates the claimed invention.

With regard to claims 5 and 11-14, the fragment obtained by amplification with primers, SEQ ID NO: 13-18, necessarily comprises a 10-mer that was present in the product according to Brennan. For example, the 20-mer recited in SEQ ID NO: 13 necessarily comprises a 10-mer that was present in the product according to Brennan.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

In response to applicant's argument that teachings of Brennan belong to the DNA sequencing domain and not to a specific *M. tuberculosis* detection domain, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the

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claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Thus, the rejection is maintained.

2. Claims 1, 2, 5, 7-9, and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by New England Biolabs 1998/99 Catalog (NEB Catalog).

With regard to claims 1, 2, and 7-9, page 121 of the NEB Catalog discloses a packaged product for sale (catalog #1255) comprising Random Primer 24. This product comprised every possible primer of 24 bases in length, and therefore inherently anticipates the claimed invention for the reasons presented above (see Brennan).

To determine the certainty that every possible 24 base primer would have been present in this product, the following calculations rely on facts provided on page pg. of the catalog, specifically the mass of 1.0 A₂₆₀ unit of single-stranded DNA and the molecular weight of single-stranded DNA per nucleotide (i.e. half the weight of a double-stranded DNA per basepair).

Random 24-mer:

Molecular weight of 24-mer:

$$24 \times 325 \text{ daltons/nucleotide} = 7,800 \text{ daltons} = 7,800 \text{ g/mol}$$

Number of possible 24-mers:

$$4^{24} = 2.8 \times 10^{14} \text{ molecules}$$

How many molecules of 24-mer in a vial sold by NEB:

$$1 \text{ A}_{260} \text{ unit} = 33 \text{ } \mu\text{g} = 3.3 \times 10^{-5} \text{ g}$$

$$3.3 \times 10^{-5} \text{ g} \div 7,800 \text{ g/mol} = 4.2 \times 10^{-9} \text{ mol}$$

$$(4.2 \times 10^{-9} \text{ mol}) \times (6.02 \times 10^{23} \text{ molecules/mol}) = 2.5 \times 10^{15} \text{ molecules}$$

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How many vials needed to sum to 1 of each possible 24-mer:

$$2.8 \times 10^{14} \text{ molecules} \div 2.5 \times 10^{15} \text{ molecules} = 0.11 \text{ vial}$$

Put another way, one vial of random 24-mer sold by NEB contains enough material to provide nearly 10 molecules of each possible 24-mer; and each vial containing 12, 9, and 6-mer primers would naturally contain even more copies of each possible primer.

Thus, NEB anticipates the claimed invention.

With regard to claims 5 and 11-14, the fragment obtained by amplification with primers, SEQ ID NO: 13-18, necessarily comprises a 24-mer that was present in the product according to NEB. For example, after 4 additional nucleotides are added to the 20-mer recited in SEQ ID NO: 13, the amplicon necessarily comprises a 24-mer that was present in the product according to NEB.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

In response to applicant's argument that teachings of NEB concerns random primer for methods (synthesis of a probe and universal DNA detection) different from the specific *M. tuberculosis* detection and discrimination method of the present invention, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Furthermore, clearly a 24-mer of complete complementarity to a 24-mer segment of SEQ ID NO: 1 would hybridize under stringent conditions, just as SEQ ID NOs: 17 and 18 hybridize to their complements under stringent conditions.

Thus, the rejection is maintained.

Allowable Subject Matter

With regard to claim 10, a search of the prior art revealed no reference teaching or fairly suggesting the oligonucleotide sequences recited in SEQ ID NOs: 13-18. Thus, the claim is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 61 is allowable for the reasons set forth in the NON-FINAL Office Action dated August 18, 2008.

Conclusion

Claim 61 is allowable.

Claims 10, 19-22, and 60 are objected to.

Claims 1, 2, 5, 7-9, and 11-14 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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